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CASE STUDY

GenturaDx IDbox

Making molecular diagnostics accessible for more patients and providers by simplifying real-time PCR testing

Ximedica partnered with an innovative startup to design and develop the first sample-in, answer-out PCR cartridge on the market on an accelerated timeline.

The Problem

Polymerase chain reaction (PCR) testing answers a wide range of medical questions to help physicians diagnose and treat: from identifying pathogenic organisms and genetic diseases to detecting biological relationships. When performed manually, the fairly simple test had been frequently showing user-to-user errors and discrepancies, and the high costs for this test had been limiting uptake in the market by labs and providers. Simplifying molecular diagnostic testing while automating the PCR diagnostic process simultaneously increases the efficacy and accuracy of PCR testing, making it both more appealing and more widely accessible for patients.

Background

A startup company based in the Bay Area, California, Gentura aspired to create the first completely self-contained PCR test on the market to simplify diagnostic testing and lower costs for labs by eliminating the need for a technician to manually run the sample preparation steps. Gentura originally had a development partner in Asia but began experiencing capability and development speed limitations. Gentura worried that their competitors were threatening their first-to-market status. Looking for a more experienced partner with PCR experience to help them accelerate their time to market, Gentura hired the local Los Gatos-based branch of Ximedica to take over development.

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Innovation Opportunity

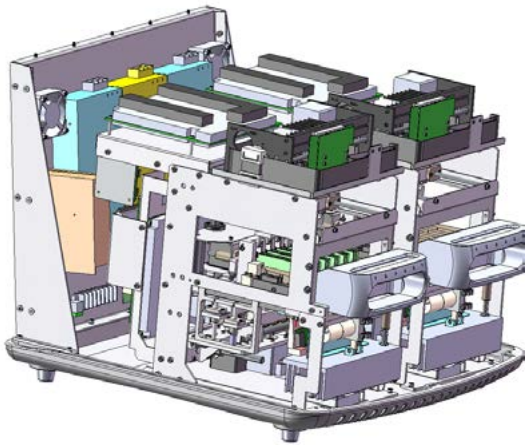
Ximedica worked with Gentura to take the previously designed sample preparation portion of the cartridge and design it into an all-inclusive, real-time PCR consumable. As the cartridge became more defined, the assay protocol drove the new instrument requirements. This led to Ximedica developing a semi-random-access system with six-color fluorescent detection and true walk-away automation.

Ximedica's Involvement

Gentura needed a working prototype device and functional version of their cartridge concept to stay ahead of the market opportunity. By partnering with Ximedica, Gentura received a fully functional system and cartridge prototype in-hand in less than a year. Ximedica continued to provide support as needed for unit builds, software support, and testing. During these later phases, Ximedica worked with Gentura to help simplify the cartridge and bring down cost of goods (COGS) to a more viable market price.

Ximedica Skills Used

- Concept Generation
- Cartridge Development
- Reagent Storage & Dispense
- Fluidic Control
- Thermal Control
- Optics
- Firmware Development
- Control Software
- Industrial Design



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Value Delivered

Ximedica developed the GenturaDx IDbox® from a partially developed sample preparation cartridge to a fully functional, sample-in-answer-out cartridge and instrument in less than a year. From this prototype, Ximedica developed an IVD instrument under engineering design controls to support Gentura through their clinical trials and eventual transfer to manufacturing. Throughout this process, Ximedica performed DFM activities to ensure that the final product was cost-effective for consumers.

The final IDbox® was an advanced real-time PCR platform with true walk-away automation due to its sample-in, answer-out capabilities. The system could run between one and twelve separate tests at once, and was engineered to accommodate for future test-menu expansion.

GenturaDx was purchased by Luminex in 2012, and was rebranded as the ARIES system. Upon its acquisition, GenturaDx had been awarded five U.S. patents for their IDbox® system.

Design process and photos depicting GenturaDx, Inc.® IDbox®.

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